



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

948720

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: CFN 2954457

June 25, 2004

Lawrence P. Fortado Sr., President  
Three Captains Sea Products, Inc.  
258 Yale Avenue  
Princeton by the Sea, California 94018

**WARNING LETTER**

Dear Mr. Fortado:

On February 19, 23-26, and March 3, 2004, we inspected your seafood processing facilities located at 258 Yale Street and 1 Johnson Pier, Princeton by the Sea, California. We found that you have serious deviations from Title 21 of the Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4).

Accordingly, your refrigerated, cooked ready-to-eat Dungeness crab is adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your HACCP deviations were as follows:

1. You must implement the monitoring procedures and record keeping system that you have listed in your HACCP plan for refrigerated cooked Dungeness crab to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring and

record keeping procedures as listed in your HACCP plan. You explained to the investigator during the inspection: "My firm is not currently using the HACCP plan." In addition, other than an informal record of the cook step, as you admitted, you neither retain nor maintain any records associated with the critical control points listed in your plan. You explained during the inspection: "We do monitor the specific boiling process on an unbound stationary pad (measuring time of the boiling process).... There are no other records generated during the process which monitor any of the critical factors identified in the HACCP plan described above."

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your HACCP plan for refrigerated, cooked Dungeness crab lists monitoring procedures at the Fresh product Storage critical control point that are not adequate to control pathogen growth. Your plan lists that "cooler temperature gauge" will be checked twice daily or that you will perform a visual check of ice on the crab each lot (i.e., when ice is used). However, FDA recommends continuous monitoring of temperature by use of a digital time/temperature data logger or recorder thermometer with a visual check of the instrument once per day or the use of a high temperature alarm with 24-hour monitoring. When ice is used for cooler storage, we recommend checking a representative number of containers at least twice per day for adequacy (i.e., coverage).
3. You must retain records of your refrigerated products at your processing facility for at least one (1) year after the date that they were prepared, to comply with 21 CFR 123.9(b)(1). However, it was observed (and documented in your affidavit) that your firm informally records only the cooking process on an unbound, undated, unsigned legal pad that you explained you do not keep but destroy (i.e., throw out). You must retain all your HACCP monitoring records for at least one (1) year for your refrigerated products.
4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However,

your firm did not monitor the condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments with sufficient frequency to ensure control as evidenced by the fact that:

- (a) On February 23, 2004, FDA observed a cooked Dungeness crab rinsing system that used waterproof gloves and a cardboard carton. The rinse water contacted the gloves and cardboard box before being applied to the cooked crab; this is a design that does not allow for proper cleaning and maintenance.

- 5. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections, to comply with 21 CFR 123.11(c). However, as you admitted during the inspection, your firm is not documenting and maintaining any records of daily sanitation monitoring for any of the eight areas of sanitation listed in 21 CFR 123.11(b).

Our investigator collected a copy of your HACCP plan for "Fresh round albacore tuna." We reviewed this plan and note that your monitoring procedures at the Fresh Storage critical control point are the same as those described for your refrigerated, cooked crab. Please be advised that FDA recommends continuous monitoring of temperature by use of a digital time/temperature data logger or recorder thermometer with a visual check of the instrument once per day or the use of a high temperature alarm with 24-hour monitoring to control histamine development at refrigerated storage. Again, when ice is used for cooler storage, we recommend checking a representative number of containers at least twice per day for adequacy (i.e., coverage).

In addition we note that your critical limits at receiving may not be adequate for controlling histamine development. Specifically, you list harvest vessel records to show that chilling on board the vessels was adequately performed. If you are a primary processor receiving fish directly from the harvest vessel and you intend to use harvest vessel records as part of your control strategy, we recommend the following be included as part of these harvest vessel records:

- Method of capture
- Date/Time of Landing
- Established date/time of death
- Air and water temperatures
- Method of cooling
- Date/Time cooling began
- Other factors as needed (i.e., internal temperature after 6 hours)
- Storage controls (i.e., ice or cooling media temperature checks)

We also recommend sensory evaluation of a representative sample of fish at receiving. Although your plan states that you check 3 fish, it is unclear that this is an adequate sampling plan to represent the incoming lot. For more information on control strategies associated with histamine forming species, including receipt of these fish by primary processors and storage practices, we suggest you refer to Chapter 7 of the Fish and Fisheries Products Hazards and Controls Guidance: 3<sup>rd</sup> Edition.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

*C D Moss, Acting D D*

*Per*

Barbara J. Cassens  
District Director  
San Francisco District